

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PHILLIP RACIES,

Plaintiff,

v.

QUINCY BIOSCIENCE, LLC,

Defendant.

Case No. 15-cv-00292-HSG

**ORDER DENYING DEFENDANT'S
DAUBERT MOTION TO EXCLUDE
PLAINTIFF'S EXPERT EVIDENCE**

Re: Dkt. No. 70

Before the Court is Defendant Quincy Bioscience, LLC's ("Defendant") motion to exclude the expert opinion of Dr. Richard T. Bazinet ("Dr. Bazinet"), which was submitted by Plaintiff Phillip Racies ("Plaintiff") in connection with his cross-motion for partial summary judgment and his opposition to Defendant's motion for summary judgment. Dkt. No. 70 ("Mot."). Defendant moves to exclude Dr. Bazinet's opinion under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702 on the grounds that Dr. Bazinet does not have the relevant experience to opine on the nutritional claims at issue in this case and, even if he did, his proffered opinion is irrelevant to the issues in this case and, regardless, is unreliable. Plaintiff has filed an opposition, Dkt. No. 78 ("Opp."), and Defendant has replied, Dkt. No. 79 ("Reply").

For the reasons set forth below, the Court **DENIES** Defendant's motion to exclude.

I. BACKGROUND

A. Procedural History

This is a putative consumer class action alleging that Defendant made false, misleading, and deceptive statements about the effects of its brain health supplement, Prevagen. Dkt. No. 21 ("Am. Compl."). Specifically, Plaintiff alleges that Prevagen does not improve memory or brain function, contrary to the claims made on the product's labeling, because the only purported active

ingredient, apoaeguorin (“AQ”), is completely destroyed by the digestive system and transformed into component parts that cannot affect the brain in a way different than other sources of dietary protein. *Id.* ¶ 3. Even if AQ was not completely destroyed during digestion, Plaintiff alleges, it would exist in such trivial amounts so as to preclude any effect. *Id.* For those reasons, Plaintiff asserts claims under California’s unfair competition law, Cal. Bus. & Prof. Code §§ 17200 *et seq.* (“UCL”), and Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.* (“CLRA”).

Defendant previously moved to dismiss the complaint, which the Court granted in part and denied in part. Dkt. No. 34. The Court held that Plaintiff could not bring UCL and CLRA claims based on the theory that Defendant failed to substantiate its brain health claims before marketing Prevagen, but could bring those claims based on a theory of false representations. *Id.* at 6-7.

Defendant has now filed a motion for summary judgment. Dkt. No. 55 (“Def.’s MSJ”). In that motion, Defendant argues that Plaintiff has failed to raise a genuine dispute as to whether its labeling claims are false, despite the expert report and deposition testimony offered by Plaintiff’s expert witness, Dr. Bazinet, opining that those claims are impossible as a matter of nutritional science. Specifically, Dr. Bazinet opines that AQ, the only active ingredient in Prevagen, “cannot improve memory or support healthy brain function, sharper mind, or clearer thinking.” Dkt. No. 64, Ex. B ¶ 8. (“Bazinet Report”). Because AQ is a dietary protein, Dr. Bazinet contends that it is digested and broken down into constituent parts, single amino acids and possibly small peptides, like all other dietary proteins. *Id.* Amino acids and small peptides cannot affect brain functioning in the manner that Defendant labeled their product because AQ is no different from ingesting any other protein, like chicken or fish. *Id.* Moreover, Prevagen provides only a trivial amount of those components as compared to other dietary sources of protein. *Id.* And even if AQ were able to enter the bloodstream intact, as Defendant claims, it could not pass through the blood-brain barrier into the brain, precluding the possibility that it could impact brain functioning. *Id.*

In response to Defendant’s motion for summary judgment, Plaintiff filed a cross-motion for partial summary judgment on the issue of falsity. Dkt. No. 63 (“Pl.’s MSJ”). Plaintiff argues that not only do Dr. Bazinet’s expert report and testimony raise a genuine dispute of material fact with respect to whether Defendant’s label claims are false, no reasonable jury could conclude that

its claims are true based on Dr. Bazinet's explanation of fundamental nutritional science. Plaintiff then filed an opposition to Defendant's summary judgment motion, essentially asserting the same arguments as its partial summary judgment motion. Dkt. No. 72.

B. Defendant's *Daubert* Motion

In response to Plaintiff's cross-motion, Defendant filed the instant motion under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to exclude any expert opinion offered by Dr. Bazinet. Defendant makes several arguments why Dr. Bazinet's expert opinion should be excluded: (1) Dr. Bazinet lacks relevant experience to opine on protein digestion and absorption in the human body; (2) even if he were so qualified, he testified at his deposition that AQ would be digested into both amino acids and small peptides, the latter of which can have biological functions beyond nutrition; and (3) Dr. Bazinet did not conduct any testing to determine how AQ itself is digested in the bodies of consumers. Not. of Mot. at 1-2. In support of these claims, Defendant offers reports from four of its own expert witnesses, who opine that proteins are not necessarily completely digested and that, even if AQ was fully digested, certain peptides can carry out non-nutritional functions. *See* Dkt. No. 70-2, Exs. B-E.

Plaintiff responds that Dr. Bazinet is a highly-qualified and experienced expert in the field of protein digestion and absorption, whose opinion that AQ is digested into materials that cannot affect the functioning or memory of the brain is reliable and plainly relevant to whether the claims that Defendant made about Prevagen were false. Dkt. No. 77 ("Opp.") at 2-5, 10-12. Plaintiff argues that Defendant's claim about AQ breaking down into peptides is a bait-and-switch attempt: the fact that AQ may be digested into small peptides as well as single amino acids is precisely what makes AQ a substance that cannot impact brain functioning once eaten. *Id.* at 6-8. Whether digested AQ has a biological effect beyond nutrition, Plaintiff continues, even if theoretically possible, is not relevant to whether AQ can impact brain functioning and memory. *Id.* at 8-10. To further support these positions, Plaintiff also submits a rebuttal report by Dr. Bazinet, challenging Defendant's factual assertions and those of its experts. Dkt. No. 77-2 ("Bazinet Rebuttal").

Defendant replies that Plaintiff mischaracterizes Dr. Bazinet's field of expertise. Dkt. No. 79 ("Reply"). At his deposition, Defendant points out that Dr. Bazinet said he was a specialist in

the fields of nutritional science and lipid metabolism, but Plaintiff now argues he is also an expert in protein digestion. *Id.* at 1-2. Defendant further contends that Dr. Bazinet's admission that AQ is broken down into small peptides as well as single amino acids undermines his opinion because, according to its experts, small peptides can have biological effects. *Id.* at 3-6. Finally, Defendant argues that a recent publication by Dr. Bazinet shows his methods are unreliable. *Id.* at 6-8.

II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admission of testimony by expert witnesses:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 thus requires that for expert testimony to be admissible, the expert be qualified, *United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000), and that his testimony be "both relevant and reliable," *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014) (en banc) (internal marks omitted). *See also Daubert*, 509 U.S. at 589.

With respect to whether a witness is qualified as an expert, "Rule 702 contemplates a broad conception of expert qualifications." *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2000) (emphasis removed). When evaluating qualifications, courts should consider a purported expert's knowledge, skill, experience, training, and education in the subject matter of his asserted expertise. *Hankey*, 203 F.3d at 1168; *see also* Fed. R. Evid. 702. If a witness has "many relevant certifications and decades of relevant experience," that will render him qualified as an expert. *See Pyramid Techs., Inc. v. Hartford Cas. Ins. Co.*, 752 F.3d 807, 814 (9th Cir. 2014).

"Relevancy simply requires that the evidence logically advance a material aspect of the party's case." *AstenJohnson*, 740 F.3d at 463 (internal marks omitted). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. *Daubert*, 509 U.S. at 591. While this standard is straightforward, relevance is "not always obvious" because "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id.*

1 Expert testimony must have a “valid scientific connection to the pertinent inquiry.” *Id.* at 592.

2 Reliability requires that an expert’s testimony has “a reliable basis in the knowledge and
3 experience of the relevant discipline.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999)
4 (internal marks and citation omitted). Courts are concerned “not with the correctness of the
5 expert’s conclusions but the soundness of his methodology.” *Primiano v. Cook*, 598 F.3d 558,
6 564 (9th Cir. 2010); *see also Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011)
7 (“[T]he trial court must act as a ‘gatekeeper’ to exclude junk science that does not meet Federal
8 Rule of Evidence 702’s reliability standards.”) (quoting *Kumho Tire*, 526 U.S. at 145).

9 Generally, to determine whether an expert’s testimony is reliable, “a court should consider
10 (1) whether a theory or technique ‘can be (and has been) tested;’ (2) ‘whether the theory or
11 technique has been subjected to peer review and publication;’ (3) ‘the known or potential rate of
12 error;’ and (4) whether it is generally accepted in the scientific community.” *AstenJohnson*, 740
13 F.3d at 463 (quoting *Daubert*, 509 U.S. at 593–94). But “depending on the type of expert
14 testimony offered, these factors may not be appropriate to assess reliability.” *Poosh v. Phillip*
15 *Morris USA, Inc.*, 287 F.R.D. 543, 546 (N.D. Cal. 2012) (citing *Kumho Tire*, 526 U.S. at 150). In
16 those cases, other factors that can be considered include whether the expert has unjustifiably
17 extrapolated from an accepted premise to an unfounded conclusion, *see General Elec. Co. v.*
18 *Joiner*, 522 U.S. 136, 146, (1997), and whether the expert has adequately accounted for obvious
19 alternative explanations, *see Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994).

20 Because the question of whether a witness is qualified to testify is a preliminary question
21 governed by Federal Rule of Evidence 104, “[i]t is the proponent of the expert who has the burden
22 of proving admissibility” by a preponderance of the evidence. *Lust By & Through Lust v. Merrell*
23 *Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996); *see also Daubert v. Merrell Dow Pharms.,*
24 *Inc.*, 43 F. 3d 1311, 1316 (9th Cir. 1995) (“*Daubert II*”) (“[T]he party presenting the expert must
25 show that the expert’s findings are based on sound science.”); *Bourjaily v. United States*, 483 U.S.
26 171, 175-176 (1987) (preponderance standard applies to Rule 104 questions). Courts have broad
27 latitude in determining the appropriate form of the *Daubert* inquiry. *AstenJohnson*, 740 F.3d at
28 463; *Primiano*, 598 F.3d at 564 (“The inquiry is a ‘flexible one,’ where ‘[s]haky but admissible

evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion.”) (quoting *Daubert*, 509 U.S. at 594, 596).

III. DISCUSSION

In essence, Defendant makes three arguments why Dr. Bazinet’s expert opinion should be excluded: (1) he is unqualified to opine about protein digestion and absorption; (2) his opinion is irrelevant, because the only issue in this case is whether AQ is digested into single amino acids, not small peptides, which indisputably can have biological functions beyond providing nutrition; and (3) his method is unreliable because he did not conduct any human testing on AQ to determine how it is digested, but instead relied on the unjustified extrapolation of general scientific principles of protein digestion. The Court finds each argument meritless, and Defendant’s motion to exclude will be denied.

A. Qualifications

Defendant first contends that Dr. Bazinet is unqualified to opine on the neurological effects (or lack thereof) of Prevagen and its alleged active ingredient AQ. Namely, Defendant points to Dr. Bazinet’s testimony that he specializes in lipids and fatty acids, but not in protein digestion. Mot. 9-10; Dkt. No. 70-3, Ex. E at 33:7-10 (“Q: Why do you say you’re not a specialist in protein digestion? A: Because we don’t focus on the technical issues in protein digestion.”). Defendant also claims that Dr. Bazinet does not have expertise in protein metabolism because he was only a “member of the lab” involved in blood-brain barrier research on protein. To determine whether Dr. Bazinet is qualified, the Court examines his credentials. *See Hankey*, 203 F.3d at 1168

Dr. Bazinet received his undergraduate Bachelor of Science degree from the University of Western Ontario in Canada where he studied foods and nutrition. Bazinet Report ¶ 1. He received a doctorate from the University of Toronto, Faculty of Medicine, in the Department of Nutritional Sciences. He then received postdoctoral training at the National Institutes of Health, National Institute on Aging, Brain Physiology and Metabolism Section in the United States. In 2006, Dr. Bazinet became a professor at the University of Toronto, Faculty of Medicine, in the Department of Nutritional Sciences, where he is a currently a tenured Associate Professor. He has since been appointed a Canada Research Chair in Brain Lipid Metabolism. He currently teaches a course

entitled “Nutritional Neuroscience,” and he runs a research program that examines how nutrition affects brain metabolism and function, including how nutrients enter the brain. *Id.* And he has received several awards for his research and teaching in the field of neurochemistry. *Id.* ¶ 4.

Dr. Bazinet has published over 80 academic articles, many of which discuss the biology of how nutrients enter and are metabolized in the brain. *Id.* ¶ 2. He holds or has held several senior editorial board positions, including: Editorial Board Member for *Nutritional Neuroscience and Nutrition and Health*; International Contributing Editor for *The Journal of the American College of Nutrition*; Associate Editor of *Frontiers in Fatty Acid and Lipid Physiology*; Senior Associate Editor of *Lipids* and Editor-in-Chief of *Prostaglandins, Leukotrienes and Essential Fatty Acids*. He has also served as an ad hoc reviewer for over 30 other academic journals. *Id.* ¶ 3.

Dr. Bazinet testified that while he focuses his research on lipid metabolism, not protein digestion, he routinely uses the concepts and theories associated with protein digestion in his research and has also conducted specific research on protein digestion hypotheses in the past. *See* Dkt. No. 64-1 at 36:3-8 (“Q: Are you an expert on protein digestion? A: So I’m not a specialist in protein digestion, but I have expertise in protein digestion.”); *id.* at 36:20-37:1 (“A: [W]e run I can’t tell you how many studies in nutrition where we’re giving lipids, proteins, carbohydrates, and then we’re measuring lipids, carbohydrates, and proteins in model systems, in tissues. So yes, I think I have expertise in nutrition, which includes protein digestion.”); *id.* at 38:1-8 (“[Y]ou use the concepts and theories associated with protein digestion for your study of lipid metabolism. But you don’t -- as a specialist of lipid metabolism, you don’t develop questions or design studies relating specifically to protein digestion. Is that right? A: That’s close.”); *id.* at 38:15-39:10 (“Q: Have you ever tested a hypothesis with respect to protein digestion? A: Yes.”); *id.* at 40:7-12 (“A: So when we formulate diets, we always have to make choices about proteins . . . [W]hen we’re using the nutritional approaches of feeding, we have to consider proteins all the time.”).

Dr. Bazinet also testified that he has conducted research on protein metabolism, which follows digestion and involves the issue of protein absorption through the blood-brain barrier. *See id.* 48:5-22 (“Q: Would you consider yourself a specialist in protein metabolism? A: So that’s a broad field to be a specialist in . . . We’ve done a lot of work on proteins at the blood-brain barrier.

1 We published on this . . . That work is very influential on what we're doing now . . . Q: So uptake
2 in the blood-brain barrier would be encompassed by the term 'metabolism'? A: Yes, yes."); *id.* at
3 53:11-54:8 ("Q: Have you personally been involved in any study designed to detect a peptide
4 crossing the [blood-brain barrier]? A: Yes. And proteins, yes . . . So when I was at the [NIH] as a
5 post-doctoral fellow, my advisor had developed a method to open the blood-brain barrier to allow
6 for proteins and peptides to cross . . . I published with [the primary investigator] several times.").

7 Notwithstanding these credentials, Defendant argues that its motion to exclude Dr.
8 Bazinet's opinion is like the one partially granted in *In re Zicam Cold Remedy Marketing, Sales*
9 *Practices, and Products Liability Litigation*, No. 09-md-2096, 2011 WL 798898, at *12 (D. Ariz.
10 Feb. 24, 2011). There, the plaintiffs alleged a variety of claims about the effects of a nasal cold
11 remedy, the active ingredient of which (zinc gluconate) allegedly caused users to lose their sense
12 of smell. *Id.* at * 1. The plaintiffs sought to introduce the medical opinion testimony of one
13 expert on several issues, including the physiology of the nose, how the product was distributed
14 within the nose, the toxicity of the product, and the effectiveness of the product. *Id.* at **3-12. In
15 relevant part, the expert had concluded that "there does not appear to be any benefit from using
16 [the active ingredient] or [the product]" in that manner. *Id.* at **5, 12. The expert was an assistant
17 professor of otolaryngology at a university, specializing in head and neck surgery (including ear,
18 nose, and throat surgery), had a master's degree in public health in the field of epidemiology, was
19 board-certified in otolaryngology, had a specialty in the area containing the part of the nose at
20 issue, and had a sub-specialty in rhinology (the study of the nose and nose diseases). The expert
21 had also been a principal investigator in a study in which he commented on the drug at issue in the
22 case. *Id.* at *3. The court found that the expert was qualified to opine on the physiology of the
23 nose, the toxicity of the product, whether the drug could reach the part of the nose at issue,¹ but he
24 could not opine on whether the product was effective. *Id.* at **3-12. In reaching that finding, the
25

26 ¹ The court did conclude that the expert could not base his opinion on one particular study of three
27 that he relied on because "the study analyzed only four participants, who used a different product
28 with a different formulation and different delivery system, and not under conditions of ordinary
use" because the study "was not intended to address clinical use and effectiveness or to assess the
delivery system." *Id.* at *6. But the problem was not the expert's qualifications. *See id.*

1 court noted only that the expert “ha[s] no background in pharmacology” or the active ingredient in
2 the product. *Id.*

3 Based on the evidentiary record before it, the Court finds that Dr. Bazinet is qualified to
4 opine on, at the very least, the fundamental tenets of protein digestion and protein metabolism as it
5 relates to protein absorption through the blood-brain barrier. Unlike the expert in *Zicam*, who had
6 no background in pharmacology, Dr. Bazinet has 20 years of educational, research, and publishing
7 experience as a nutritionist and neuroscientist. *See Hankey*, 203 F.3d at 1168. While Defendant is
8 correct that none of Dr. Bazinet’s publications explicitly include the phrase “protein digestion,”
9 the Court finds that the question of how dietary proteins are digested into their constituent parts in
10 humans fairly falls within the purview of a nutritional scientist and neuroscientist with a B.S.,
11 Ph.D., an NIH fellowship, a tenured professorship, and a national research chair in a related field.
12 *See* Bazinet Report ¶¶ 1-4. To that effect, Dr. Bazinet averred in his rebuttal expert report that
13 “[j]ust like I do not need to test if a ball will fall to the earth upon releasing it from my hand, I do
14 not need to specifically test [AQ] to conclude that it will be digested[.]” Bazinet Rebuttal ¶ 36. In
15 any case, Defendant does not establish with evidence that protein digestion is outside the fields of
16 nutritional science and neuroscience or that Dr. Bazinet does not have expertise in those fields.
17 Accordingly, the fact that Dr. Bazinet specializes in his career on lipid metabolism as opposed to
18 protein digestion does not mean that he does not have sufficient expertise in the field of protein
19 digestion to opine about a seemingly fundamental issue of nutritional science. *See In re Silicone*
20 *Gel Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 915-16 (C.D. Cal. 2004) (holding
21 that a lack of sub-specialization does not render an expert in the general field unqualified).

22 With respect to Dr. Bazinet’s qualification as an expert in the realm of protein metabolism,
23 Defendant’s position is significantly more precarious. Dr. Bazinet holds a national research chair
24 position in the related sub-specialty of brain lipid metabolism and did significant research at the
25 NIH, one of the foremost medical research organizations in the United States, specifically on the
26 topic of protein metabolism in the human brain. Bazinet Report ¶ 1. Defendant’s argument that
27 Dr. Bazinet is unqualified because there is no evidence that he was actually involved in that NIH
28 research given that he testified he was only a “member of the lab” working on protein absorption

through the blood-brain barrier is a matter of semantics, at best. Regardless, Dr. Bazinet testified that he personally was involved with this NIH research. Dkt. No. 64-1 at 53:11-54:8.

Accordingly, the Court finds that Dr. Bazinet is qualified to offer testimony on whether dietary proteins like AQ are digested into component amino acids and small peptides as well as whether AQ or those component parts could pass through the blood-brain barrier in the brain to affect brain functioning, specifically given the quantity of dietary protein available in Prevagen.

B. Relevance

Defendant next contends that Dr. Bazinet's opinion is irrelevant. Defendant argues that the Court decided in its Order on Defendant's motion to dismiss that the only issue in this case with respect to the falsity element of Plaintiff's claims was whether AQ was digested completely into single amino acids, not whether it could also be digested into small peptides. Mot. at 10-14.

The Court disagrees. In partially denying Defendant's motion to dismiss, the Court noted that "[i]f Plaintiff successfully proves that [AQ] in [Prevagen] is destroyed by the human digestive system or is of such a trivial amount that it cannot biologically affect memory or support brain function, he will be able to affirmatively prove the falsity of Defendant's Product claims." Dkt. No. 34 at 6. These were simply examples of how Plaintiff could prove its claims of falsity, not an order confining the scope of the case to those precise issues. Moreover, the Court did not say anywhere that "completely destroyed" meant "digested into single amino acids."

Plaintiff's complaint similarly does not limit the scope of the falsity claim to the issue of whether AQ is digested entirely into single amino acids. Plaintiff has alleged that the "ingestion of Prevagen cannot and does not have any effect on brain function or memory." Am. Compl. ¶ 3. Plaintiff has therefore broadly alleged that Defendant's claims about Prevagen and AQ are false because they are biochemically impossible. That encompasses Dr. Bazinet's entire expert opinion. It is true that Plaintiff also alleged that "[Dr. Bazinet] has concluded that . . . Prevagen cannot work as represented because [AQ], the only purported active ingredient in Prevagen, is completely destroyed by the digestive system and transformed into common amino acids no different than those derived from other common food products such as chicken, cold cuts, hamburgers, etc." *Id.* One fair reading of the phrase "completely destroyed by the digestive system and transformed into

common amino acids” is that it was an informal summary of forthcoming scientific testimony in an expert report. Another fair reading is that, it is an accurate characterization of protein digestion, in which a complex protein structure is denatured by enzymatic processes into its component parts, all of which are composed of common amino acids. *See* Bazinet Report ¶¶ 10-11 (“[W]ell-established science establishes that [AQ], like all other proteins, is fully digested before it hits the bloodstream. Significantly, the only notable exceptions are some small peptides (the term peptide refers to molecules of about 50 amino acids or less, and upon digestion they consist, predominately, of 2 or 3 amino acids), which [AQ] is not, and even these small peptides with unique properties are only absorbed at a rate of about 1%.”); *id.* ¶¶ 12-14 (“But then these products go through additional digestion in the intestinal cells and are even further reduced to amino acids as a result. *Within the intestine a series of peptidases ensures that any peptides that have entered are converted into amino acids for secretion into the blood* where they can be taken up by the liver and metabolized or passed through to the circulatory system.”) (emphasis added). Either way, the complaint does not limit the scope of the case in the way Defendant claims.

Moving past these procedural scoping issues, there is no real question that Dr. Bazinet’s opinion testimony is relevant under *Daubert* because it “logically advance[s] a material aspect” of Plaintiff’s case. *See AstenJohnson*, 740 F.3d at 463. If Dr. Bazinet is correct that (1) AQ cannot reach the brain intact because it is digested into smaller, non-active components before it enters the bloodstream, (2) the amount of those non-active components is trivial in comparison to any common source of dietary protein, or (3) even if AQ is not digested and can reach the brain intact, it cannot pass through the blood-brain barrier to enter the brain and affect brain functioning, then Plaintiff will have logically advanced his claim that Defendant’s label representations are false.²

Accordingly, the Court finds that Dr. Bazinet’s testimony is relevant to this case.

C. Reliability

Finally, Defendant argues that Dr. Bazinet’s extrapolation about the effects of digestion on

² Defendant’s argument that Dr. Bazinet cannot rule out that AQ could create peptides that could affect brain functioning goes to the reliability and weight of his testimony, not its relevance. This contention is therefore addressed below.

AQ is unreliable because it relies on unsound general principles of nutritional science. Namely, Dr. Bazinet opines that because AQ is a dietary protein, it is fully digested into single amino acids and possibly small peptides, neither of which can affect brain functioning in a manner different from other sources of dietary protein. Bazinet Report ¶¶ 9-14. Defendant argues, through three of its own experts on protein digestion, that it is not true that all dietary proteins are digested entirely into their component parts. Mot. at 12-16. If that is true, then Defendant contends that Plaintiff's extrapolation about AQ is unjustified. Furthermore, even if all dietary proteins are digested into single amino acids and small peptides, Defendant contends that Dr. Bazinet has admitted that the manner by which proteins are digested varies by protein, making it possible that the digestion of AQ creates small peptides with an impact on brain functioning. To that effect, Defendant points to a U.S. patent that it characterizes as asserting the existence of such a peptide. Reply at 5-6. In sum, Defendant argues that because Dr. Bazinet does not know if AQ is digested into small peptides that might affect brain functioning, he cannot opine about the effects of AQ.

The Court finds that both Dr. Bazinet's principles and his method of extrapolation from those principles to reach a conclusion about the effect of protein digestion on AQ are reliable. To begin, the Court's role is not to determine the truth of Dr. Bazinet's opinion on the digestion of AQ at this stage. Instead, the purpose of *Daubert* is for the Court to serve as a "gatekeeper" to prevent "junk science" from being admitted. *Ellis*, 657 F.3d at 982; *Primiano*, 598 F.3d at 564. To that end, Dr. Bazinet's opinion, as challenged, is based on two general scientific principles: (1) all dietary proteins are digested into amino acids and possibly small peptides; and (2) amino acids and small peptides from dietary proteins cannot improve brain functioning. Bazinet Report ¶¶ 9-14. The Court considers whether each principle is reliable under the *Daubert* standard in turn.

According to Dr. Bazinet, the first principle above—that dietary proteins are digested into amino acids and possibly small peptides—is based on well over 100 years of research and is a consensus opinion in the field of nutritional science. Bazinet Rebuttal ¶ 8 ("[A]fter well over a hundred years of digestion research a general rule is accepted and followed by the scientific community – unless otherwise shown, all dietary proteins are digested into amino acids and possibly some small peptides."). In support of this claim, Dr. Bazinet cites to several treatises and

1 publications. *See* Bazinet Report ¶ 11 nn. 7-12. One treatise Dr. Bazinet cites explains that:

2 After ingestion, proteins are denatured by the acid in the stomach,
3 where they are also cleaved into smaller peptides by the enzyme
4 pepsin . . . The proteins and peptides then pass into the small
5 intestine, where the peptide bonds are hydrolyzed by a variety of
6 enzymes . . . The resultant mixture of free amino acids and small
7 peptides is then transported into the mucosal cells . . . After
8 intracellular hydrolysis of the absorbed peptides, the free amino
9 acids are then secreted into the portal blood . . . or are further
10 metabolized within the cell itself.

11 Institute of Medicine of the National Academies, *Dietary Reference Intakes for Energy,*
12 *Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* 599 (2005).

13 Each of Defendant's three experts on protein digestion testified that they agreed with this
14 general principle at their depositions. *See* Dkt. 75-2 ("Goodman Depo.") at 86:24-87:6 ("Q: [T]he
15 question is that isn't it true that if [AQ] is like other dietary proteins, that when it is digested with
16 the pancreatic enzymes, there is a resultant mixture of free amino acids and small peptides? A: As
17 it travels along the intestinal tract, one would expect that mostly it would be digested to free amino
18 acids or smaller peptides."); Dkt No. 75-3 ("Bisardi Depo.") at 86:24-87:6 ("Q: . . . [In his expert
19 report, Dr. Bazinet] states, 'Collectively, these enzymes break down proteins, including [AQ], into
20 amino acids and possibly some small peptides for absorption into the intestine.' Do you agree
21 with that statement? A: Again, I agree with the part excluding AQ [] because he doesn't cite any
22 literature. I know of no literature that demonstrates this for [AQ]. It could apply to [dietary]
23 proteins in general."); Dkt. No. 75-4 ("Pezzone Depo.") at 64:15-19 ("Q: Dr. Pezzone, do you
24 agree that, generally speaking, most dietary proteins are hydrolyzed in digestion down to common
25 amino acids and peptides? A: Through the course of the [gastrointestinal] tract, probably so.").

26 It should be noted that before testifying that he agreed with Dr. Bazinet's general principle
27 of protein digestion, one of Defendant's protein digestion experts, Dr. Bisardi, contended that
28 bromelain, a mixture of proteins extracted from pineapple stems, can enter the blood as a complete
protein after digestion. Dkt. No. 69-3 ("Bisardi Report") ¶¶ 23-25. In his expert report, Dr.
Bazinet responded that the test used in the underlying studies that reached that conclusion is not
"specific enough to detect whether it is an intact molecule or a peptide that is being observed."
Bazinet Report ¶ 28. Each of Defendant's protein digestion experts, including Dr. Bisardi, agreed

1 with that assessment. *See* Goodman Depo. at 52:9-22 (“Q: And you said earlier that it was tough
 2 to measure the peptides; is that correct? A: It is difficult . . . [T]he difficult is that as proteins get
 3 digested into different length fragments, you cannot necessarily say is this an intact protein or it’s
 4 a digested fragment of the protein.”); Pezzone Depo. at 76:25-78:9 (“Q: I think we established that
 5 [one type of digestion test], when it confirms the presence of something related to the protein
 6 that’s been ingested, that it’s not sensitive enough to determine whether or not what it has detected
 7 is either intact protein or a fragment of that protein, correct? A: Correct. Yeah. Q: Okay. And
 8 that’s similar for several of the other [digestion tests] that have been employed in studies that you
 9 cited in your report, correct? A: Correct.”); Bisardi Depo. at 60:1-61:8 (“Q: [D]o you understand
 10 that in these articles that you have cited in your report, the authors discuss the fact that the ELISA
 11 assay they used cannot determine whether or not they are seeing a protein or whether they are
 12 seeing fragments of a protein; correct? A. If fragments mean -- possibly mean peptides, yes, that
 13 is correct. Q. So when they get a positive hit on an ELISA assay, they just know they have seen
 14 something from the protein they are studying. They don't know whether it's an intact protein or
 15 whether it's a peptide; correct? A. Correct.”). In light of this consensus opinion that the studies
 16 showing that intact proteins exist in the bloodstream after digestion, the Court cannot find that the
 17 existence of bromelain makes Dr. Bazinet’s general principle of protein digestion unreliable.

18 Another of Defendant’s experts, Dr. Pezzone, did maintain that although proteins will be
 19 digested if they remain in the gastrointestinal tract, intact proteins could be absorbed without being
 20 digested before the end of the digestion process. *See* Dkt. No. 69-2 (“Pezzone Report”) ¶¶ 15-19
 21 (“[T]he absorption of small amounts of dietary proteins from the gastrointestinal tract has been
 22 observed[.]”); Pezzone Depo. at 181:3-182:17. The only basis for this opinion in the record is a
 23 single academic article from 1985 for which there is no citation sufficient to locate it. *See* Pezzone
 24 Report ¶ 16 (“Paganelli, Husby 1985”). Furthermore, Dr. Pezzone defined “protein” as “a large
 25 peptide” and “[t]herefore, the term ‘protein’ as used in this report includes large peptides that may
 26 be derived from an ingested protein.” *Id.* n. 2 (emphasis added). If that definition is applied, it is
 27 not at all clear to the Court that Dr. Pezzone’s report materially differs from Dr. Bazinet’s opinion
 28 that dietary proteins are broken down from their initial form before absorption. In any case, and

critically for *Daubert* purposes, Dr. Pezzone does not argue that Dr. Bazinet’s first principle on protein digestion has not been “tested,” “subjected to peer review and publication,” or “generally accepted within the scientific community.” *See AstenJohnson*, 740 F.3d at 463. For that reason, and in light of the consensus among the other experts who have testified in this case, the Court finds that Dr. Bazinet’s first protein digestion principle is reliable under the *Daubert* standard.

Dr. Bazinet’s second principle of protein digestion—that single amino acids and small peptides derived from dietary proteins during digestion cannot improve brain functioning—relies on two sub-claims about protein metabolism. First, single amino acids created from the digestion of a dietary protein are indistinguishable from any other amino acids derived from other digested dietary protein and do not affect brain functioning, especially in trivial amounts. Bazinet Report ¶¶ 15-16. Second, small peptides derived from dietary proteins, while potentially varying between digested proteins, cannot affect brain functioning because they can neither pass through the blood-brain barrier (with a few exceptions for peptides made within the body and synthetic peptides) nor affect brain functioning from outside the brain. Bazinet Report ¶¶ 22-24; Bazinet Rebuttal ¶¶ 3(c), 3(e). In support of his claim that small peptides are generally not capable of crossing the blood-brain barrier (or “BBB”), Dr. Bazinet cites more than a half-dozen publications. *See, e.g.*, William M. Pardridge, *The Blood-Brain Barrier: Bottleneck in Brain Drug Development*, NeuroRx®: The Journal of the American Society for Experimental NeuroTherapeutics, Jan. 2005, at 3-14 (“[T]he transport of small molecules across the BBB is the exception rather than the rule, and 98% of all small molecules do not cross the BBB.”). Exceptions include “endogenous peptides, modified proteins, and peptidomimetic monoclonal antibodies.” William M. Pardridge, *Drug and Gene Targeting to the Brain with Molecular Trojan Horses*, National Review Drug Discovery, Mar. 2002, at 131-39. Dr. Bazinet has explained that peptides derived from dietary proteins, which are exogenous, unmodified, and not antibodies, do not fall into these exceptions. Bazinet Report ¶ 24.

In response, Defendant offers the expert report of Dr. Brian Spencer, who opines that it is possible for small peptides to cross the blood-brain barrier through receptor-mediated transcytosis (in which small peptides “piggy-back” through the blood-brain barrier on an antibody), if they are “cell-penetrating peptides,” or if the blood-brain barrier has been damaged by a neurodegenerative

disorder such as Alzheimer's disease. *Id.* ¶¶ 18-27. But Dr. Spencer significantly qualified these opinions at his deposition. With respect to receptor-mediated transcytosis, Dr. Spencer testified that the studies he relied upon to conclude that a peptide could piggy-back across the blood-brain barrier relied on bioengineering not used in AQ. Dkt. No. 75-5 ("Spencer Depo.") at 221:9-228:2. Moreover, that process occurred through injection not digestion. *Id.* at 224:19-225:11. To wit, he testified that he is unaware of any peptide produced by a dietary protein that has even been found to be subject to receptor-mediated transcytosis. *Id.* at 127:12-17. With respect to cell-penetrating peptides, Dr. Spencer testified that there are only 20 or so that have been identified and that he has no reason to believe that AQ creates them through digestion. *Id.* at 231:7-22. And with regard to his "leaky" blood-brain barrier opinion, Dr. Spencer testified that his claim was merely an untested hypothesis. *Id.* at 237:10-19. In fact, Dr. Spencer went on to testify: "These are all -- these are all hypotheses, yes. This is a reasonable hypotheses of tests. That's what I'm trying to state there. It's reasonable enough to try and test." *Id.* 237:19-22. Based on these statements, the Court finds that Dr. Spencer's opinion does not undermine the prima facie reliability of Dr. Bazinet's principle about the metabolism of small peptides. Again, Dr. Spencer does not argue that Dr. Bazinet's opinion has not been "tested," "subjected to peer review and publication," or "generally accepted within the scientific community." *See AstenJohnson*, 740 F.3d at 463.


Accordingly, because Dr. Bazinet's underlying principles are reliable, his extrapolation that AQ cannot affect human brain functioning because it is a dietary protein is justified.

IV. CONCLUSION

For the foregoing reasons, the Court hereby **DENIES** Defendant's *Daubert* motion to exclude the opinion testimony of Plaintiff's expert witness, Dr. Richard P. Bazinet.

IT IS SO ORDERED.

Dated: 9/30/2016


HAYWOOD S. GILLIAM, JR.
United States District Judge